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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/836,075	04/21/1997	GEERT MAERTENS	INNS:004/KAM	5845
23117	7590	04/11/2005	EXAMINER	
NIXON & VANDERHYE, PC 1100 N GLEBE ROAD 8TH FLOOR ARLINGTON, VA 22201-4714			ZEMAN, MARY K	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 04/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

08/836,075

**Applicant(s)**

MAERTENS ET AL.

**Examiner**

Mary K. Zeman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 75, 79 and 81-87 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 75, 79, 81-87 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 75, 79, 81-87 are pending in this application. Claims 86-87 are newly added.

Applicant's arguments filed 12/27/04 have been fully considered but they are not completely persuasive.

#### ***Claim Rejections - 35 USC § 112***

Claims 75, 79, 86-87 (and claims 81-86 newly dependent thereon) are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 86 and 87, the recitation "part of at least 5 contiguous nucleotides" is confusing. Is the part 5 nucleotides, or is applicant claiming a portion (part) of the 5 nucleotides? It would appear that random hexamer polynucleotide primers would meet the limitations of these claims. Random hexamers, by definition, comprise every 6 nucleotide sequence which can be made by the four standard nucleotides. It would appear that the polynucleotide of the claim need only encode a single amino acid?

In claims 75, 79, 86 and 87, it is not clear if the complement is required to be the fully complementary full length sequence, or whether something shorter or less exact is intended to be encompassed.

In claim 81, and 85, the complement of the HCV polynucleotide does not encode HCV polypeptides. It is not clear what would be encoded, and the specification is not enlightening.

Claims 86, 87 and claims 81-85 in as far as they read on claims 86 and 87 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

In view of the indefiniteness of the rejected claims, the broadest reasonable interpretation of the claims is being utilized herein. Claims 86 and 87 are being interpreted as a polynucleotide comprising at least 5 nucleotides which also must encode one listed amino acid.

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The specification discloses SEQ ID NO: 1, 3, 5 etc. odd numbers to 105, and sequences encoding SEQ ID NO: 107-207 which correspond to specific portions of HCV genomic sequences that fall within certain subtypes of HCV. Claims directed to these specific SEQ ID NO's would meet the written description provisions of 35 USC 112, first paragraph. However, claims 86 and 87 are directed to encompass any polynucleotide sequence (of at least five nucleotides) which happens to encode one of the listed amino acids. **None** of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

The basis for the written description rejection has been provided in previous actions.

#### ***Claim Rejections - 35 USC § 102***

Claims 86, 87 and 81-85 are rejected under 35 USC 102(e) as being anticipated by Houghton et al. (US 5,350,671 previously of record.)

Applicant asserts the claimed sequences are not those of Houghton which discloses HCV 1a sequences. However, claim 86 and 87 still read on short polynucleotide sequences (5 or less?) which also comprise certain amino acids. Claim 86 subtype 7 comprises S2646, subtype 1g recites A2719, subtype 3g recites at least L2756, D2752, E2751 and R2757 which are each disclosed by Houghton. Houghton discloses long and short polynucleotides comprising the disclosed sequences, as well as encoded polypeptides, vectors and host cells. Houghton also discloses complements of the disclosed sequences.

Houghton et al discloses a composite HCV polyprotein sequence at figure 66 which corresponds to the composite nucleotide sequence of Fig 62. This polyprotein discloses an amino acid sequence having at least an S at position 2646. Houghton's sequence also has A2719, E2751, D2752, L2756 and R2757. Houghton discloses polynucleotides, short and long, which encode HCV polyproteins and parts thereof. Houghton discloses vectors comprising the sequences, host cells comprising the vectors, and methods of making recombinant polypeptides. Houghton discloses peptides, long and short, which are portions of the polyprotein sequences disclosed. As the rejected claims are unclear as to what exactly they encompass, Houghton also discloses multiple short polynucleotides of HCV each of which, at some point, encodes one of

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the amino acids listed in claims 86 and 87. As such, this reference meets the limitations of the rejected claims.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (571) 272 0723

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, PhD can be reached on (571) 272 0718. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.


Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

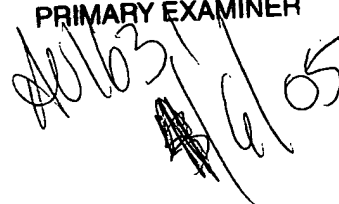
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enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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MARY K. ZEMAN  
PRIMARY EXAMINER

  
11/6/05